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EXAMINER	
NIEBAUER, RONALD T	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,172	APPELDOORN ET AL.	
	Examiner	Art Unit	
	Ronald T. Niebauer	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,18-23 and 30* is/are pending in the application.

4a) Of the above claim(s) *2,5-10 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,11,12 and 18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

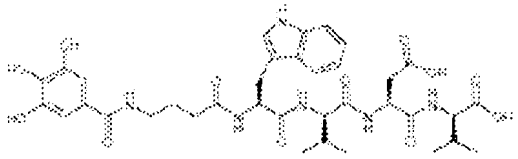
Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (claims 1-12,18-23) and the species named peptide 28 (see Table 3 at page 21) of structure:



in the reply filed on 11/2/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that applicant states that claims 10 and 30 read on the elected species. However, claim 30 is not a properly dependent claim or is unclear. Claim 30 recites that R1 is 3,4,5-trihydroxyphenyl and Z is attached to X via a spacer. However in claim 1, X is described as being substituted with R1-(Z)n (i.e. X is R1-(Z)n). If X is R1-(Z)n it is unclear how Z is attached to X since the claim implies that Z is attached to R1-(Z)n. Likewise claim 10 is unclear since it also states that Z is attached to X.

Section 803.02 of the MPEP highlights the examination of Markush type claims:

> Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability....
> .... should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species.

> The examination will be extended to the extent necessary to determine patentability of the Markush-type claim.

In the instant case, the elected species named peptide 28 (see Table 3 at page 21 as shown above) was found to be free of the prior art. Since no claim is drawn solely to the elected species no claim is indicated as allowable. The examiner extended the search to another species (see 102 rejection below) and as such has extended the search to the extent necessary to determine patentability of the Markush-type claim.

Claims 2,5-10,30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/2/07.

Claims 13-17,24-29 have been cancelled.

Claims 1,3-4,11-12,18-23 are under consideration.

Information Disclosure Statement

The information disclosure statement filed 2/8/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. In the instant case no copy of the non-patent literature listed as A3 (Molenaar et al.) has been provided. The IDS has been placed in the application file, but the information referred to therein has not been considered.

Specification

The disclosure is objected to because of the following informalities: applicant has appropriately provided sequence listings. However, each listing of a particular sequence in the specification should be referenced with the appropriate sequence identifier (see Table 2 and page 4 line 2, for example). See 37 CFR 1.821(d).

Appropriate correction is required.

Drawings

The drawings are objected to because the drawings are not labeled. The specification pages 4-5 refers to figures 1-6, however there are 8 pages of figures and no figure labels. As such, the figures are not correctly described (see MPEP 608.01(f)). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-4,11-12,18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and dependent claims recite a compound...which is a derivative of a peptide represented by sequence X(Ax)mA3A1A2A1Y. It is unclear if the claim is drawn to a compound of sequence X(Ax)mA3A1A2A1Y, or if the claim is drawn to a derivative of sequence X(Ax)mA3A1A2A1Y. The claim scope of a derivative of sequence X(Ax)mA3A1A2A1Y would be broader than a compound drawn to sequence X(Ax)mA3A1A2A1Y. Further, claim 12 recites that the composition comprises one or more derivatives. It is unclear if claim 12 is drawn to peptides of sequence X(Ax)mA3A1A2A1Y or derivatives of sequence X(Ax)mA3A1A2A1Y.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3-4,11-12,18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a

method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to a compound of formula X(Ax)mA3A1A2A1Y (claim 1).

(1) Level of skill and knowledge in the art:

The level of skill in the art is high.

(2) Partial structure:

Claim 1 recites a compound of formula X(Ax)mA3A1A2A1Y. Although unclear (see 112 2nd above) claim 1 and dependent claims have been interpreted as being of sequence X(Ax)mA3A1A2A1Y not a derivative of the sequence. X can comprise 1-6 D- or L-amino acids residues or analogues thereof; Ax can be any of 4 D- or L- amino acids; A3 can be any of 2 D- or L- amino acids; A1 can be any of 2 D- or L- amino acids; A2 can be a specific D- or L-amino acid. In considering the possible variability if X is 6 amino acids long and Y is 11 amino acids long (not even considering analogues) there are (40^6x8x4x4x2x4x40^{11}) over 1.75×10^{30} combinations possible when not even considering analogues or variations at R1 and R2. Hence, there is substantial variability in the genus. It is noted that the dependent claims do not substantially change the size of the genus.

However, the examples provided (some of which do not fall within the claimed genus) in Tables 1-3 include less than 40 species. Since the genus includes over 1.75×10^{30} combinations, the species do not even represent a millionth of a percent of the variability.

Since there are a substantial variety of compounds possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

Claim 1 recites that the compound has affinity to human P-selectin. However, there is not a disclosed correlation between structure and function for all of the compounds and no specific direction is provided to identify portions that bind P-selectin. In particular, no common sequence or common core is taught (only A2 is limited to a single amino acid, all other positions could be

a variety of amino acids) for all the compounds. Residues X and Y can be analogues, however no common sequence is taught for all the analogues. No specific direction is provided as to what analogues would have affinity to human P-selectin. As such, one of skill in the art would not recognize which compounds would have affinity to human P-selectin.

(5) Method of making the claimed invention:

The specification (example 1-3) describes synthesis of compounds of the invention, however the compounds are not representative of the variability of the claimed genus.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1 is/are broad and generic, with respect to all possible compounds encompassed by the claims. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the polypeptides beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed

that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-4,11-12,18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kogan et al. (US 6,087,330).

Kogan teach cyclic peptides (claim 1) specifically cyclic peptides of SEQ ID NO:25 (claim 14, column 6 lines 44-45,52-53). The disulfide cyclic peptide of SEQ ID NO:25 has the sequence Cys-Trp-Val-Asp-Val-Cys. In comparison to the current invention (of sequence X(Ax)mA3A1A2A1Y see claim 1) which states in claim 1 that X and Y may form a cyclic structure, m is 0, A3 is Trp (compare claim 4 of the current invention), A1 is Val (compare claim 3 of the current invention), A2 is Asp, X marks the N-terminal side and comprises an amino acid analogue (i.e. a portion of a disulfide bonded cysteine), Y marks the C-terminal side and comprises an amino acid analogue (i.e. a portion of a disulfide bonded cysteine), X and Y together contain the group R1-(Z)n where n is 0 and R1 is a C2-C8 alkyl with carbon replaced by sulphur. The peptide of Kogan is cyclic (compare claim 11 of the current invention). Kogan teach compositions of the peptides (column 8 lines 52-column 9 line 46). Specifically Kogan

teach compositions comprising a peptide (column 8 line 53-55) (compare claim 12 of the current invention); pharmaceutical compositions (column 8 line 52-55) (compare claim 18 of the current invention); compositions for intramuscular delivery (column 8 line 65) (compare claim 19 of the current invention); compositions in solid form (column 8 line 61) (compare claim 20 of the current invention); compositions for nasal administration (column 8 line 67) (compare claim 21 of the current invention); compositions for inhalation (column 9 line 40-41) (compare claim 22 of the current invention); and compositions with a ligand for targeted delivery (column 9 line 5-6) (compare claim 23 of the current invention).

It is noted that claim 1 of the current invention recites that the compound has affinity to human P-selectin. Section 2112.01 of the MPEP states that products of identical compositions can not have mutually exclusive properties. Since the peptide of Kogan meets the claim limitations it must necessarily have the claimed function.

It is noted that although unclear (see 112 2nd above), claim 1 and dependent claims have been interpreted such that the compound is of sequence X(Ax)mA3A1A2A1Y not a derivative of the sequence.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,3,4,11,12,18-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8,16-21,30,35-43 of copending Application No. 10/488,509 ('509). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1, for example, of '509 is drawn to a compound of the same formula X(Ax)A3A1A2A1Y (with overlapping residues at A1,A2,A3,Ax; including A1 is valine (compare claim 3 of the instant invention) and A3 is tryptophan (compare claim 4 of the instant invention)) as claim 1 of the instant invention. Specifically, claim 1 of '509 is drawn to a Cys-Cys disulfide bonded compound which meets the limitations of the instant invention with X marking the N-terminal side and comprising an amino acid analogue (i.e. a portion of a disulfide bonded cysteine), Y marking the C-terminal side and comprising an amino acid analogue (i.e. a portion of a disulfide bonded cysteine), X and Y together containing the group R1-(Z)n where n is 0 and R1 is a C2-C8 alkyl with carbon replaced by sulphur. '509 also teach compositions. Claims 16-21 of '509 correspond to claims 18-23 of the instant invention.

It is noted that although unclear (see 112 2nd above), claim 1 and dependent claims have been interpreted such that the compound is of sequence X(Ax)mA3A1A2A1Y not a derivative of the sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1,3,4,11,12,18-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/558,492 ('492). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1, for example, of '492 is drawn to a compound of the same formula X(Ax)mA3A1A2A1Y (with overlapping residues at A1,A2,A3,Ax; including A1 is valine (compare claim 3 of the instant invention) and A3 is tryptophan (compare claim 4 of the instant invention)) as claim 1 of the instant invention. Although the claims of '492 include extra moieties, the moieties are within the scope of the claims since X and Y of the current invention can be analogues or can be substituted. The claims of '492 are also drawn to compositions, for example claim 26.

It is noted that although unclear (see 112 2nd above), claim 1 and dependent claims have been interpreted such that the compound is of sequence X(Ax)mA3A1A2A1Y not a derivative of the sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1,3,4,11,12,18-23 are directed to an invention not patentably distinct from the claims of commonly assigned 10/488,509, and 10/558,492 recited above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/488,509, and 10/558,492, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rtn

ANISH GUPTA
PRIMARY EXAMINER